

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESALE PRICE  
LITIGATION

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) MDL No. 1456  
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) CIVIL ACTION: 01-CV-12257-PBS  
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THIS DOCUMENT RELATES TO ALL  
CLASS ACTIONS

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) Judge Patti B. Saris  
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**PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO SUPPLEMENT THE  
RECORD WITH EVIDENCE "RECENTLY MADE AVAILABLE AND HIGHLY  
RELEVANT TO THE COURT'S CLASS CERTIFICATION DECISION"**

## I. INTRODUCTION

Plaintiffs object to defendants' effort to supplement the record in this Court with material that (1) could have been obtained in a timely fashion in this Court; (2) contains new arguments that could have been made before and should have been made; and (3) is evidence obtained not from this case but from a proceeding plaintiffs are not a party to.

To the extent the Court considers this material, plaintiffs maintain that the materials fully support class certification of a proposed Part B class that includes individuals who paid a co-pay for Part B Medicare drugs. Defendants' supplemental evidence concerns the payment history of a plaintiff in an Arizona case who was prescribed Lupron. Lupron is the subject of a certified class action in which a simple claim form was provided to each class member. As explained below, that claim form completely eliminates the proof problems postulated by defendants. In *Lupron*, over 13,000 claims have been received from individual consumer class members, claiming \$27,273,498 in Lupron purchases. In certifying the class, Judge Stearns rejected the argument that individualized proof should defeat class certification. This Court should reject this belated argument as well.

### A. The Defendants' New Argument Should Not Be Permitted

Defendants did not previously oppose the Part B class on the grounds that certification of a Part B class that included individuals was inappropriate due to the need for individualized payment inquiry. Defendants have made no showing that this was an argument they could not have made earlier pursuant to the class certification briefing schedule, and at a time when the plaintiffs could have responded with both facts and expert analysis.<sup>1</sup> Nor have defendants given

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<sup>1</sup> Defendants did not identify this purported need for individualized proof in answers to interrogatories, nor have they ever supplemented their interrogatory answers to identify such issues.

any explanation as to why they did not proceed to gather this type of information in this proceeding in a timely process.

Instead, defendants began planning for this argument by proceeding to elicit discovery on this issue in early 2005 in another AWP case pending in Arizona. Class counsel in this case are not counsel in this case and did not participate in the discovery. It would be patently unfair to accept this late evidence, from another case, in support of a new argument in opposition to class certification. The Court should deny the motion to supplement.

**B. Courts Do Not Deny Class Certification Based on Individualized Damage Proceedings**

Defendants now claim that because, according to their proof, it may be difficult to trace an individual Part B Medicare payor's payment history, that the Court should not include such individuals in any certified Part B class. Judge Stearns rejected this argument and this Court should do so as well.

**1. Individual damages will be calculated by using a standard formula and readily-available data**

While Phase II proposes an individualized procedure for determining damages, it does not present the individualized proof defendants attempt to portray as necessary. First, as plaintiffs demonstrated in the Medicare Part B setting, they will be able to prove on a class-wide basis that AWP was the basis for reimbursement. This has not been seriously contested. With AWP as the established class-wide benchmark, Dr. Hartman will assess the amount of the illegal spread on a per drug basis, which will then serve as the yardstick for measuring individual damages in Phase II. Given that Class members will be able to identify each AWP-based

payment from claims data and other documentation that is readily available,<sup>2</sup> application of a standard formula can be readily deployed to calculate specific damages. For the Medicare Part B Co-Pay Class, the information submitted will consist of documentation showing the amount of 20% co-pays made for AWPIDs. The Third-Party Payer and Co-Pay RICO Class members will submit contracts with PBMs and providers and claims data showing each reimbursement made for AWPIDs on the basis of AWP, along with the reimbursement amount.<sup>3</sup> The specific damage calculations will be conducted through computer processing, permitting a level of automation and efficiency that Defendants simply ignore.

In the Part B context where it is not seriously contested that *all* Class members paid based on the uniform AWP benchmark, substituting the fraudulent AWP for what the non-fraudulent benchmark should have been – a “plug and play” formula – reveals the precise amount of damage on a transaction-by-transaction basis.

## **2. The Swanston-Lupron Evidence Fully Supports Certification**

It is ironic that out of the 324 drugs at issue in the AMCC (now called the “SAC”), defendants use Lupron as an example to preclude individuals from being part of the Medicare Part B class. In *Lupron*, Judge Stearns carefully considered the Rule 23 criteria and certified a class. *In re Lupron Mktg. & Sales Practices Litig.*, 228 F.R.D. 75, 2005 U.S. Dist. Lexis 9027 (D. Mass. 2005). In certifying the class, the Court found that commonality was satisfied because plaintiffs’ evidence, consisting of Dr. Hartman’s economic analysis, satisfied the Court that “virtually every purchase of Lupron® during the class period was influenced to one degree or another by defendants’ manipulation of the published AWP.” *Id.*, at \*45, n.29. In so doing,

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<sup>2</sup> See App. 1(e); Hartman Reply Declaration (“HRD”) at Section III.C, ¶ 23, pp. 27-30. Even Young has conceded that Class member claims data reveals the basis upon which *each* reimbursement was made and the amount of the reimbursement. See Young Decl., Ex. 17d.

<sup>3</sup> HRD at Section III.C, ¶ 23, pp. 27-30.

Judge Stearns rejected the intervenors' suggestion that certification was not appropriate because some of the individual purchasers might not have been paid for Lupron based upon AWP. Judge Stearns found that such "needle and haystack problems" did not warrant denial of certification, particularly where plaintiffs' economic evidence demonstrated across-the-board price inflation. The same expert and the same basic theory of common impact has been presented in this case as well.

The *Lupron* certification order actually demonstrates how the individualized proceedings defendant hypothesizes will not in fact happen in this case. Judge Stearns approved a proof of claim for each consumer as follows:

Each Consumer Proof of Claim shall be accompanied by evidence of payment for Lupron® as called for in the Consumer Proof of Claim attached as an Exhibit to the Notice Plan. Consumer Class Members shall be required to certify (1) the time period over which they, or the Consumer Class Member on whose behalf they are submitting a Proof of claim, took or were administered Lupron® and (2) the total out-of-pocket payments for Lupron® (including any co-pay or cash payments therefore) net of any reimbursements from insurers or any other source during the Class Period. In addition, Consumer class Members shall be required to provide ONE of the following as evidence of payment for Lupron® during the Class Period.

(i) a copy of a single written prescription for Lupron® during the Class Period;

(ii) a copy of a single receipt evidencing payment of a co-pay or cash payment for Lupron® during the Class Period.

(iii) a single EOB (explanation of benefits) form from an insurer or other health plan evidencing a co-pay or cash payment for Lupron® during the Class Period;

(iv) a single cancelled check evidencing payment of a co-pay or cash payment for Lupron® during the Class Period;

(v) a letter from the Consumer Class Member's physician stating that the consumer was administered Lupron® and paid a

co-pay or cash payment therefore and stating the amount paid during the Class Period; or

(vi) a notarized statement indicating that Consumer Class Member paid a co-pay or cash payment for Lupron® during the Class Period and setting forth the total out-of-pocket payments for Lupron® during the Class Period.

*In re Lupron Mktg. & Sales Practices Litig.*, 345 F. Supp. 2d 135, 142-43 (D. Mass. 2004).

This proof of claim form completely eliminates the “individualized” process defendants proffer as necessary for each of the individual elderly class members in this case. If a *Lupron*-type of claims form is utilized here, no individualized proceeding would be needed. A class member would furnish a receipt that he or she paid for a Part B drug, or would provide a statement from a doctor that he or she paid for a Part B drug or would furnish the type of proof as required by the *Lupron* Court. In the Part B Class, defendants have not defeated plaintiffs’ common proof that all Part B drugs are reimbursed based upon AWP. Hence, when the claim form is properly completed, there is no basis to conclude that individualized proceedings are needed because common proof will have been presented that all prices have been inflated. If a Class member paid for a Part B drug, then he or she paid at an inflated price.

Indeed, if one applies this process to Mr. Swanston, ***none*** of the steps defendants undertook would be required. Mr. Swanston would not be able to make a claim as he has no proof he paid for Lupron, hence he is not a class member and the purported individualized proceeding would be unnecessary. The claims process in the *Lupron* case has worked smoothly. Thirteen thousand five hundred ten claims have been received to date by the claims administrator in that case. Of the 12,922 claims processed to date, consumers have identified a total of \$27,273,498 in purchases or co-payments by the Lupron consumer class.<sup>4</sup>

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<sup>4</sup> See Declaration of Ed Notargiacomo.

## II. CONCLUSION

Defendants attempt to defeat the inclusion of individuals in the Part B Class, based solely on one example of the facts relating to a person who is not even a Class member, is misplaced. If anything, the *Lupron* example highlights why the Part B class should include such individuals. Indeed, as Judge Stearns noted, with respect to individual payors,

The superiority analysis dovetails with the predominance analysis. The issue here is one that lies at the very heart of the invention of the class action as a litigation vehicle: few, if any, members of the settlement class have incurred damages in an amount sufficient to justify the costs of pursuing an individual action. That fact alone makes a class action the only means by which most class members can obtain redress. Even if the claims could be prosecuted individually, their sheer number would make it unlikely that any significant number would be resolved during the lifetimes of the consumer class members. The court finds that under the circumstances, a class action is superior to any other mechanism for adjudicating this case (including joinder).

*In re Lupron*, 228 F.R.D. 75, 2005 U.S. Dist. Lexis 9027, at \*58.

DATED: July 21, 2005

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**CERTIFICATE OF SERVICE**

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing, **PLAINTIFFS' RESPONSE TO DEFENDANTS' MOTION TO SUPPLEMENT THE RECORD WITH EVIDENCE "RECENTLY MADE AVAILABLE AND HIGHLY RELEVANT TO THE COURT'S CLASS CERTIFICATION DECISION"** to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on July 21, 2005, a copy to Verilaw Technologies for Posting and notification to all parties

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